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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/416,828 | 10/12/1999 | WILLIAM STEVE AMMONS | 27129/33638A | 6675 |

7590

11/12/2002

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EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 11/12/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/416,828

Applicant(s)

AMMONS ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10 is/are rejected.
- 7) ☒ Claim(s) 8, 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Claims 1-5, 8-10 are pending and being examined. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

Maintained Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 1-5, 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing the duration of bradycardia by administering BPI, does not reasonably provide enablement for a method of reducing the duration of cardiac arrhythmia by administering a BPI protein product.

Applicants argue that this rejection should be withdrawn because Applicants have fully supported the recitation of "BPI protein product" because they teach of wide variety of

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biologically active analogs and variants of BPI which are the subject of co-owned U.S. patents and applications which are incorporated by reference, and that the merits of the present application warrant the scope of the claims. Applicants arguments have been fully considered but they are not persuasive. The present claims are of essentially limitless breadth because, as

5 used herein, "BPI protein product" includes biologically active polypeptide analogs or variants of either bactericidal/permeability-increasing protein or biologically active fragments thereof (page 4, lines 23-29). Biologically active analogs and variants of BPI include, BPI protein products wherein one or more amino acid residues have been replaced by a different amino acid (page 6, lines 10-12). There are no limits on the number and type of amino acids that may be replaced.

10 The claims encompass essentially any and all compounds that achieve the desired results, including those unrelated to BPI, because all of the amino acids in BPI could be replaced. The specification lacks guidance for making, and working examples of, compounds unrelated to BPI that achieve the desired results. The scope of claims does not bear a reasonable correlation to scope of enablement provided by the present specification, even in view of analogs and variants
15 of BPI which are the subject of co-owned patents and applications which incorporated by reference, because the claims encompass compounds unrelated to BPI.

The rejection of the claims over "treating ... cardiac arrhythmia" is withdrawn upon further consideration because the claims are limited to reducing "the duration of cardiac arrhythmia resulting from intestinal ischemia/reperfusion injury", which Figure 6 demonstrates,
20 and intestinal ischemia/reperfusion injury induces bradycardia, as demonstrated in Figure 4.

Claims 1-5, 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants argue that this rejection should be withdrawn because Applicants have fully supported the recitation of "BPI protein product" because they teach of wide variety of biologically active analogs and variants of BPI which are the subject of co-owned U.S. patents and applications which are incorporated by reference, and that the merits of the present application warrant the scope of the claims. Applicants arguments have been fully considered but they are not persuasive. The present claims are of essentially limitless breadth because, as used herein, "BPI protein product" includes biologically active polypeptide analogs or variants of either bactericidal/permeability-increasing protein or biologically active fragments thereof (page 4, lines 23-29). Biologically active analogs and variants of BPI include, BPI protein products wherein one or more amino acid residues have been replaced by a different amino acid (page 6, lines 10-12). There are no limits on the number and type of amino acids that may be replaced. The claims encompass essentially any and all compounds that achieve the desired results, including those unrelated to BPI, because all of the amino acids in BPI could be replaced. The claims are directed to or encompass a genus of "BPI protein products" The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to BPI. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a

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significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus.

The general knowledge and level of skill in the art do not supplement the omitted description

5 because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, BPI and rBPI₂₁ cys alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed
10 genus.

Claims 1-5, 10 are rejected under 35 U.S.C. 112, second paragraph, over the recitation of "BPI protein product". Applicants argue that this rejection should be withdrawn because Applicants have fully supported the recitation of "BPI protein product" because they teach of
15 wide variety of biologically active analogs and variants of BPI which are the subject of co-owned U.S. patents and applications which are incorporated by reference, and that the merits of the present application warrant the scope of the claims. Applicants arguments have been fully considered but they are not persuasive. As used herein, "BPI protein product" includes biologically active polypeptide analogs or variants of either bactericidal/permeability-increasing
20 protein or biologically active fragments thereof (page 4, lines 23-29). Biologically active analogs and variants of BPI include, BPI protein products wherein one or more amino acid residues have been replaced by a different amino acid (page 6, lines 10-12). There are no limits

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on the number and type of amino acids that may be replaced. The claims encompass essentially any and all compounds that achieve the desired results, including those unrelated to BPI, because all of the amino acids in BPI could be replaced. The metes and bounds are not clearly set forth.

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Conclusion

Claims 8, 9 are objected to as being dependent upon a rejected base claim.

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All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

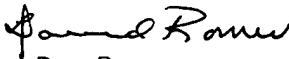
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
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DSR
NOVEMBER 10, 2002